Safety Signal

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Abstract

Aim

The **primary aim** of this study is to detect safety signals for all vaccines in the VAERS database using the Proportional Reporting Ratio (PRR), and to create a public search engine for vaccine safety signals.

PRR is a metric used by both the European Medical Association and by the Centre for Disease Control for detecting safety signals. However, both the EMA and the CDC have failed to publish their PRR analyses, even though this information is vital for informed choice. This study seeks to carry out an independent PRR analysis of all of the VAERS data available. A single dataset is created by concatenating the VAERS datasets for every year from 1990 to 2023, and the proportional reporting ratios are calculated for each symptom associated with each vaccine. The result is a useful look-up tool called **"Safety Signal"**, where a user can look-up all the safety signals for any vaccine in rank order.

The **null hypothesis** : The **"Safety Signal"** dataset is used to investigate if any vaccines generate a safety signal for the symptom of thrombosis. The null hypothesis is that all vaccines are equally safe, and so there will be no significant differences between vaccines in the PRR values for thrombosis. (95 % confidence interval). Any significant PRR values are confirmed by 5 new criteria for safety signal detection – MSC (multiple sample consistency), SSC (Same Symptom Consistency), RSC (Related Symptom Consistency), RBC (Related Biomarker Consistency), and RTC (Related Treatment Consistency. The **conclusion :** High PRR values for thrombotic events following COVID-19 vaccination are found, and these high PRR values are consistent across multiple related symptoms and treatments, so the null hypothesis is rejected.

Resources

Safety signal detection is of critical interest to the public, so the data has been made accessible through downloadable CSV files and as an online search engine.

Safety Signal (online) : [1]
Summary of Signals (online) : [2]
Datasets for easy use (csv | excel) : [3]
Datasets for analysts (csv | excel) : [4]
Coding (python) : [5]

1 Introduction

1.1 What is the PRR ratio ?

PRR calculates the percentage of reports where a particular symptom is recorded following administration of a drug A, and sees if this varies significantly from the percentage of reports where the same symptom is recorded after administration of drug B.

The PRR is defined as the ratio between the frequency with which a specific adverse event is reported for the drug of interest (relative to all adverse events reported for the drug) and the frequency with which the same adverse event is reported for all drugs in the comparison group.

> *For example, suppose that nausea was reported 83 times for a given drug of interest, out of 1356 adverse events reported for the drug. Thus the proportion of adverse events of nausea for this drug is 83/1356 = 0.061. Suppose that we wish to compare the drug of interest to a class of drugs, for which nausea was reported as an adverse event 1489 times, out of 53789 total adverse events reported for drugs in the class. Thus, nausea was reported with proportion 1489 / 53789 = 0.028 for the class of drugs. The PRR in this case is 0.061 / 0.028 = 2.18. This tells us that nausea was reported more than twice as frequently (among all adverse event reports) for the drug of interest compared to drugs in the comparison group.*
>
> **Wikipedia, (2023), "Proportional Reporting Ratio" [6]**

Cases	Drug of interest	Comparator
Event of interest	a	c
Other events	b	d

$$PRR = \frac{a/(a+b)}{c/(c+d)}$$

Figure 1: PRR formula

1.2 Who uses PRR ratio for Signal Detection?

PRR is used for the detection of serious drug reactions (SDRs) by "the European Medical Association (EMA) in their EudraVigilance Data Analysis System

> *Different statistical methods to generate SDRs are in use. In the EudraVigilance Data Analysis System, the Proportional Reporting Ratio (PRR) has been implemented in the first release. Other methods will be considered for future implementation.*

European Medicines Agency,(2006), "Guideline on the Use of Statistical Signal Detection Methods in the Eudravigilance Data Analysis System" [7]

This method is also used by the Center for Disease Control (CDC) in the USA. On January 29th of 2021 the CDC released a document titled 'Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19' (for official use only) which announced the CDC's intention:

> *CDC will perform Proportional Reporting Ratio (PRR) analysis [...], excluding laboratory results, to identify AEs that are disproportionately reported relative to other AEs. [...] To determine if results need further clinical review, consider if clinically important, unexpected findings, seriousness, specific syndrome or diagnosis rather than non-specific symptoms*

Centers for Disease Control and Prevention, (2021), "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021) [8]

1.3 What Criteria Define a Strong Signal ?

1.3.1 CDC Criteria :

The CDC uses the following criteria –

1. Symptom events >= 3
2. PRR >= 2
3. Chi-squared >= 4 OR
4. Lower limit of 95% confidence interval of PRR >= 2

Ref : [9] Excel spread sheets released by CDC through Freedom of Information request

These are exactly the same criteria that were used by Evans and his team who introduced the PRR signal detection method in 2001 [10]. In 2002 Puijenbroek [11] found that symptom events >= 10 resulted in greater consistency across different methods for detecting safety signals - so in this study I will be using symptom events >= 10 as my criteria. This will serve to remove "noise" from the results.

1.3.2 PRR >= 2

The higher the value of PRR, the stronger the signal. A PRR greater than 2 means that a symptom occurs at more than twice the frequency with the drug of interest compared to the comparator drug/s. This is regarded by the CDC as a strong signal, so PRR >= 2, is the level used by the CDC to detect a safety signal.

We can calculate the limits of random variation of the PRR. If the lower limit of variation is still > 2, then we can be confident that the PRR exceeds 2 by a significant margin. The lower limit of variation is called the lower confidence limit, and it is given by the equation – [12]

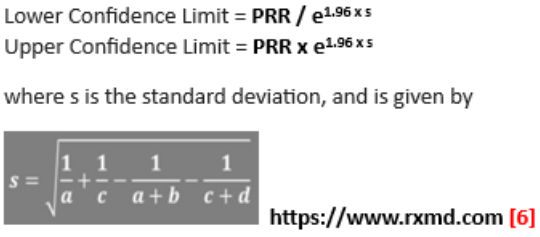

Figure 2: Confidence limits for PRR

1.4 What Criteria Confirm a Strong Signal ?

1.4.1 Large samples

A signal is regarded as strong if it is based on a large sample of data. CDC accepts a signal if the number of reports of a symptom (symptom events) is greater than or equal to 3. The larger the number of symptom reports, the greater our confidence. As stated above, the criteria used in this study is a more stringent one - the number of reports must be greater than or equal to 10.

1.4.2 Multiple Sample Consistency (MSC) :

Sample variation is a possible cause of a high PRR. To rule this out we can take multiple independent samples of equal size to see if there is consistency in the PRR across samples. If the PRR remains consistently high across all samples then we can have greater confidence in the PRR score.

1.4.3 Same Symptom Consistency (SSC) :

This is where different forms of the same symptom are consistently reported with a high PRR. The table below shows 25 different forms of thrombosis. If a medication has a high PRR score for causing cerebral thrombosis, then our confidence in that score is increased if the medication also has high scores for many other forms of thrombosis. This consistency is strong evidence that the effect is real.

Same Symptom Consistency may be quantified by the number of symptoms that it is consistent across. In this example, COVID 19 vaccines produce high PRR scores (> 2) across 43 different symptoms of thrombosis.

In addition to this, COVID 19 vaccines have an INF score across 46 additional symptoms (shown on the next page). An INF score is where COVID 19 vaccines are THE ONLY vaccines in the database producing that particular symptom. We may therefore add this score to the previous one, and the total score comes to 89.

In the database there are only 94 symptoms in total containing the word thrombosis, and COVID 19 has high PRR scores (>2) for 89 of them. Other vaccines never have more than 4. The consistent occurrence of a high PRR across many related symptoms supports the conclusion that a symptom is occurring disproportionately.

1.4.4 Related Symptom Consistency (RSC)

This is where related symptoms are consistently reported with a high PRR. Related symptoms would include terms such as clots, infarctions, occlusions, and embolisms.

1.4.5 Related Biomarker Consistency (RBC)

In addition, any particular illness or condition is evidenced by several biomarkers or biological indicators. Consequently, if a high PRR is obtained for

a particular condition, then we would expect bio-markers and effects for that condition to have high PRR scores also. When multiple biomarkers for a condition have high PRR scores, then we can have greater confidence in the high PRR score for the condition.

1.4.6 Related Treatment Consistency (RTC)

Every condition requires different medical treatments. For example a cardiac disorder may be treated with chest X-rays, electrocardiogram, cardiac imaging, cardiac operation, cardiac pacemaker, cardiac stress test, cardiac rehabilitation therapy, cardiac ventriculogram, assays etc. So, when associated treatments also have high PRR scores, then our confidence in a high PRR score for a particular condition increases.

1.5 Previous Studies

Clinical Studies : The possibility of finding serious levels of dis-proportionality in symptoms for COVID vaccines is suggested by several clinical studies - which show that COVID vaccines induce the body to produce a spike protein that acts as a cardio-vascular toxin. [13] [14] [15]

Previous Studies of Dis-proportionality with COVID Vaccines : In previous studies significant dis-proportionality has been found when comparing COVID vaccines with flu vaccines using data from the VAERS database for 2021 [16] . The vaccines were compared using cardiovascular symptoms. In a second study, COVID vaccines were compared with Flu vaccines using data from the World Health Organisation. Once again the vaccines were compared using cardiovascular symptoms, and significant dis-proportionality was found. [17]

These findings led to a third study were COVID vaccines have also been compared to flu vaccines using full range of symptom categories. World Health Organisation data was used in this study. Significant dis-proportionality was found for reproductive, cardiac and endocrine symptoms [18].

COVID vaccines have been compared with 7 other vaccines, and with common medications such as paracetamol and aspirin. The drugs were compared for the full range of symptom categories. Significant dis-proportionality was found - especially for reproductive and cardiac symptoms. [19]

CDC Analysis of Dis-proportionality with COVID Vaccines : The CDC itself released results of their own PRR analysis of COVID vaccines (2020-2022 compared to all non-mRNA vaccines (2009-2022) in the VAERS database. Their analysis was not published publicly, but was obtained through legal coercion using Freedom of Information. Very high dis-proportionality was found. Their analyses can be viewed here. [9]. Their spreadsheets can be viewed here [20] and here [**?**]

Prelude to the Current Study : Since COVID vaccine have been found to be associated with serious symptoms, this suggested that other vaccines might also have serious side-effects. Consequently, all 98 vaccines in the VAERS database were compared using the symptom of mortality (death) for the period 1990 to 2022. Significant differences in mortality were found between them.

Current Study : In the current study, I create a dataset of PRR values for every symptom of every vaccine recorded in the VAERS database, then demonstrate the dataset by using it to determine if safety signals are generated with COVID-19 vaccines for the symptom of thrombosis.

1. **Safety Signal Definition :** A safety signal is **defined** by - PRR >= 2, LCI >= 2, minimum number of symptom records >= 10.
2. **Safety Signal Confirmation :** A safety signal is **confirmed** by consistency of PRR across samples, symptoms and treatments - MSC, SSC, RSC, RBC and RTC.

Due to the critical nature of the information uncovered, the data for all vaccines has been made publicly available through downloadable CSVs and an online interface (Safety Signal) enabling users to read off the symptoms for each vaccine, sorted by PRR, and read off the vaccines for each symptom, sorted by PRR.

2 Data Preparation

2.1 Data Source

Vaers Vax csv files and **Vaers Symptoms** csv files were downloaded from the VAERS-AWARE website [21] for all years from 1990 to 2023, and read into a Jupyter Notebook using Python. The same files can also be downloaded from the VAERS website [22]

2.2 Concatenation and Data Preprocessing

Vaers Vax files were concatenated into a single data file called **"datasetvax"**, with two columns – VAERS ID and VAX TYPE. Rows with duplicate VAERS IDs were removed entirely, because they represent instances where a person received two or more different vaccines at the same time. Taking multiple medicines makes it hard to attribute adverse effects to a particular medicine, so these records were removed.

Vaers Symptom files were concatenated into a single data file called **"datasetsymptoms"**, with two columns – VAERS ID and SYMPTOM1. Rows where SYMPTOM1 was null were removed.

2.3 Merging

The datsetvax table was merged with the datasetsymptoms table on the common field of VAERS ID, so we end up with -

1. 9020372 records
2. 2144512 unique VAERS IDs
3. 16849 unique symptoms
4. 99 unique vaccines
5. averaging 4.2 symptoms per VAERS ID

The resulting dataset lists every symptom and its associated vaccine, and the strength of the safety signal for that symptom.

2.4 Converting Raw Data into Safety Signals

1. **Counting :** A count of each symptom for each vaccine was obtained by creating a pivot table.

2. **Converting Counts to PRR Scores :** The symptom frequencies were then converted into PRR scores. The resulting dataset lists every vaccine as a separate column, and each row is a different symptom.

3. **Calculating standard deviation (S) of the PRR :** The standard deviation was calculated using the formula above, then the 95% lower confidence limit of the PRR was calculated.

4. **Filtering for number of events :** The resulting dataset of Lower Confidence Limit values was then filtered so only those LCI values > 2 remained. In addition, the LCI values were further filtered so only those values corresponding to atleast 10 events remained.

5. **Transposing :** This dataset was then transposed to generate a dataset where every symptom is a separate column, and each row is a different vaccine.

The datasets created above can be downloaded as spreadsheets and CSV files here [4]

Finally, an online interface was created that enables users to enter a vaccine, then view all its symptoms ranked by PRR. They can also enter a symptom, and see all the vaccines with that symptom ranked by PRR. The interface can be viewed here [1]

A webpage showing the python code used in this study is available online here [23]

3 Data Search

3.1 PRR Magnitude (PRR)

The Transposed Dataset was used. The symptom column for ”thrombosis” was selected and sorted by PRR from high to low to show those vaccines with the highest PRR for thrombosis. The PRR scores were recorded.

3.2 Multiple Sample Consistency (MSC)

Python code was used to generate 100 random samples of COVID vaccine symptoms (each sample size = 40,000 symptoms), and these were compared to 100 random samples of FLU vaccine symptoms (each sample size = 40,000 symptoms), so they were matched exactly on size. The aim was to see if the high PRR for thrombosis following COVID19 vaccination was consistent across multiple samples.

3.3 Same Symptom Consistency (SSC)

The PRR Dataset was used. The symptoms column was filtered for ”thrombosis”.The PRR scores were then read from the COVID19 column and recorded. Same symptoms included -

1. ”Venous thrombosis limb”
2. ”Retinal vascular thrombosis
3. ”Superior sagittal sinus thrombosis
4. ”Cerebral venous sinus thrombosis
5. ”Ophthalmic vein thrombosis
6. ”Pulmonary artery thrombosis
7. ”Peripheral artery thrombosis
8. ”Atrial thrombosis
9. etc.

3.4 Related Symptom Consistency (RSC)

The PRR Dataset was used. The symptom column was filtered for terms related to thrombosis. The PRR scores were then read from the COVID19 column and recorded. Related terms included -

1. ”embolism”
2. ”infarction”
3. ”occlusion”

4. ”aneurysm”
5. ”haemorrhage”
6. ”bleeding”
7. ”ischaemia”
8. ”haematoma”
9. ”stroke”
10. ”arteriosclerosis”
11. ”phlebitis”

Additional terms that could be used are -

1. ”coagulation”
2. disorders with key word ”vascular”
3. disorders with key word ”arterial”
4. disorders with the key word ”alveolar”
5. disorders with the key word ”capillary”
6. ”red blood cell agglutination”
7. ”abnormal clotting factor”

3.5 Related Biomarker Consistency (RBC)

The PRR Dataset was used. The symptom column was filtered for the tests and indicators used to identify thrombosis. Each element of the clotting cascade involves specific molecules that can be tested for. The PRR scores were then read from the COVID19 column and recorded. Indicators included -

1. ”d-dimer”
2. ”coagulation test”

Additional terms that could be used are -

1. ”fibrin”
2. ”coagulation factor V”
3. ”coagulation factor VII”
4. ”coagulation factor VIII”
5. ”coagulation factor inhibitor assay”
6. ”coagulation time”
7. ”duplex ultrasound”

8. ”venography”
9. ”vascular imaging”
10. ”vascular resistance”
11. ”vascular insufficiency”

3.6 Related Treatment Consistency (RTC)

The PRR Dataset was used. The symptom column was filtered for treatments used to treat thrombosis. The PRR scores were then read from the COVID19 column and recorded. Treatments included -

1. ”thrombectomy”
2. ”anticoagulant therapy”
3. ”catheters”
4. ”stents”

Additional terms that could be used are -

1. ”blood thinners”
2. ”thrombolytics”
3. ”vena cava filter”
4. ”stockings”
5. ”compression”
6. ”graft”
7. ”vascular operation”
8. ”vascular procedure complication”
9. ”shunt”

4 Results

The VAERS data for COVID 19 monovalent vaccines [3] shows that there are 483 **adverse** symptoms where PRR >=2, LCI >= 2 and number of events (A) >= 10. These symptoms fall into general categories. Here are the number of symptoms for each of the top 3 categories -

Vascular Disorders	164
Cardiac Disorders	85
Infections	28

This shows that cardio-vascular damage defines the nature of the largest group of safety signals associated with COVID monovalent vaccines– accounting for about 50% of all the safety signals. (Note that this is not a count of symptoms per se, rather it is a count of those symptoms that qualify as safety signals.)

In the following pages you will see that COVID 19 monovalent vaccines are associated with safety signals for every form of vascular disease including thrombosis, infarctions, embolisms, aneurysms, occlusions, strokes, haematomas, ischaemias, bleeding, haemorrhages and arteriosclerosis.

In fact, out of all 99 vaccines in the VAERS database, COVID 19 monovalent vaccines have the highest LCI (lower confidence limit of the PRR) for each of these symptoms. This means that it has the highest values of Proportional Reporting Ratio in which we can have confidence.

A consistency of these high values across related symptoms, related biomarkers and related treatments is found, confirming a strong association between COVID vaccines and vascular disorder.

4.1 PRR for Thrombosis

Here are the results comparing the COVID 19 vaccine with the other 98 vaccines for the symptom of "thrombosis" (as a single word). Covid 19 vaccine has a very high PRR score of 8.76 for Thrombosis. It is the only vaccine where the lower confidence limit (LCI) exceeds 2.

VAX_TYPE	PRR	LCI	A
COVID19	8.76105081	7.96799892	9817
EBZR	4.602034548	0.651511966	1
UNK	0.809453261	0.62399788	57
HPV4	0.577844959	0.476370055	104
COVID19-2	0.406311707	0.311744976	55
MER	1.862205966	0.26282777	1
ANTH	0.324572566	0.179709134	11
HEPAB	0.367340078	0.175104015	7
6VAX-F	0.999910757	0.140989555	1
FLUR4	0.388896871	0.125435651	3
HPV9	0.192423651	0.100098184	9
FLUX(H1N1)	0.267369026	0.086231048	3
FLU3	0.114441531	0.082503887	36
FLUX	0.132026433	0.080854993	16
PPV	0.121507708	0.080709795	23
HPV2	0.175442996	0.078806372	6
HEP	0.09935497	0.062573626	18
IPV	0.209187694	0.052317596	2
FLUN(H1N1)	0.201686561	0.050441273	2
VARZOS	0.071690231	0.050390908	31
HEPA	0.116718607	0.048573221	5
FLUA3	0.191370325	0.04786082	2
HPVX	0.178919365	0.044746455	2
RUB	0.287159812	0.040457975	1
FLUN4	0.160282063	0.04008481	2
DTAP	0.093891061	0.035233485	4

Figure 3: Vaccines sorted by PRR for thrombosis

4.2 Multiple Sample Consistency (MSC)

Here are the results comparing 100 random samples for COVID vaccine with 100 random samples for FLU vaccine (each sampl of size 40,000 symptoms). The figure below exhibits the results for the first 25 samples. The PRR > 7 for all 100 samples.

PRR	Covid	Flu
23.00	Counts = 69	3
11.60	Counts = 58	5
20.67	Counts = 62	3
7.88	Counts = 63	8
13.50	Counts = 54	4
7.00	Counts = 56	8
4.91	Counts = 54	11
18.67	Counts = 56	3
17.25	Counts = 69	4
12.60	Counts = 63	5
10.00	Counts = 50	5
13.50	Counts = 54	4
10.50	Counts = 63	6
12.50	Counts = 50	4
7.57	Counts = 53	7
7.50	Counts = 60	8
19.33	Counts = 58	3
11.86	Counts = 83	7
11.00	Counts = 55	5
19.33	Counts = 58	3
14.20	Counts = 71	5
10.33	Counts = 62	6
32.00	Counts = 64	2
9.50	Counts = 57	6
18.25	Counts = 73	4

Figure 4: Multiple Sample Consistency (COVID vax vs Flu vax : Counts for symptom of thrombosis for each random sample of symptoms (n = 40,000)

These samples are drawn randomly from a dataset of 6,452,217 COVID 19 vaccination symptoms and 269,177 Flu vaccination symptoms.

4.3 Same Symptom Consistency (SSC)

There are 94 "thrombosis" symptoms listed in the database, and COVID 19 vaccines generate a safety signal for 32 of them, where PRR >= 2 and lower confidence limit (LCI) >=2.

SYMPTOM	PRR	LCI	A
Venous thrombosis limb	43.68344	21.77704	878
Cerebral venous sinus thrombosis	32.09543	17.70948	887
Deep vein thrombosis	11.03028	9.841463	8480
Superficial vein thrombosis	14.81228	8.711423	521
Ophthalmic vein thrombosis	26.40244	8.44313	199
Thrombosis	8.761051	7.967999	9817
Peripheral artery thrombosis	19.02568	7.846996	239
Venous thrombosis	9.668733	6.428007	583
Cerebral venous thrombosis	10.68549	6.142614	349
Jugular vein thrombosis	15.92107	5.903055	160
Cerebral thrombosis	8.509538	5.863888	620
Mesenteric vein thrombosis	13.13488	5.830326	198
Portal vein thrombosis	10.5658	5.787114	292
Retinal vascular thrombosis	40.99676	5.720189	103
Pulmonary thrombosis	7.244087	5.521997	1001
Retinal vein thrombosis	11.59964	5.460618	204
Transverse sinus thrombosis	15.39037	4.891978	116
Superior sagittal sinus thrombosis	35.02635	4.879274	88
Arterial thrombosis	10.50791	4.302274	132
Coronary artery thrombosis	7.4431	3.939785	187
Aortic thrombosis	15.52304	3.814239	78
Thrombosis with thrombocytopenia	7.120256	3.638601	161
Carotid artery thrombosis	9.254122	3.401501	93
Pelvic venous thrombosis	5.937232	3.309456	179
Pulmonary artery thrombosis	23.48358	3.253598	59
Cardiac ventricular thrombosis	10.21602	3.223661	77
Cerebral artery thrombosis	8.657082	3.177527	87
Subclavian vein thrombosis	5.572375	3.022605	154
Axillary vein thrombosis	6.666948	2.431075	67
Atrial thrombosis	16.3191	2.244714	41
Basilar artery thrombosis	6.766455	2.111851	51
Vena cava thrombosis	4.378294	2.01962	77

Figure 5: Same Symptom Consistency (COVID monovalent : thrombosis)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then no other vaccine generates a safety signal for any of these symptoms of thrombosis.

4.4 PRR for Infarction

There are 39 ”infarction” symptoms listed in the database, and COVID 19 monovalent vaccines generate safety signals for 14 of these symptoms (LCI >= 2). 8 of these infarction symptoms are cerebral - causing significant brain damage, cognitive deficit and ”brain fog”.

SYMPTOM	PRR	LCI	A
Pulmonary infarction	13.196118	7.600249	431
Cerebral infarction	6.6410492	5.619683	2436
Ischaemic cerebral infarction	8.6371806	4.582071	217
Thalamic infarction	10.348696	4.578871	156
Cerebellar infarction	8.5575752	4.53925	215
Splenic infarction	9.6853177	4.280927	146
Acute myocardial infarction	4.5067911	3.96417	2876
Brain stem infarction	7.8610284	3.863709	158
Myocardial infarction	4.2085862	3.822882	4811
Lacunar infarction	5.9704013	3.328284	180
Embolic cerebral infarction	19.503311	2.693081	49
Basal ganglia infarction	8.2258863	2.58216	62
Infarction	3.7243932	2.522401	262
Thrombotic cerebral infarction	16.319097	2.244714	41
Haemorrhagic cerebral infarction	11.144749	1.516304	28
Haemorrhagic infarction	8.3585619	1.124303	21
Spinal cord infarction	2.3218227	0.976591	35
Omental infarction	2.2554849	0.660979	17
Optic nerve infarction	1.4926003	0.495379	15
Retinal infarction	1.7247826	0.491495	13
Bone infarction	2.7861873	0.342784	7
Embolic cerebellar infarction	2.7861873	0.342784	7

Figure 6: Related Symptom Consistency (COVID monovalent : infarctions)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then only COVID bivalent vaccine generates a safety signal - for ”acute myocardial infarction (LCI = 4.058)

4.5 PRR for Embolisms

. There are 32 "embolism" symptoms listed in the database, and COVID 19 monovalent vaccine generates a safety signal for 7 of them.

SYMPTOM	PRR	LCI	A
Pulmonary embolism	12.35622	11.20169	12790
Embolism	12.97567	7.762506	489
Peripheral embolism	42.19084	5.888375	106
Embolism arterial	7.960535	2.916243	80
Embolism venous	5.492769	2.890888	138
Cerebral artery embolism	4.59942	2.327782	104
Microembolism	15.12502	2.076593	38
Retinal artery embolism	8.756589	1.180286	22
Coronary artery embolism	4.776321	0.621039	12
Femoral artery embolism	3.582241	0.45383	9
Septic pulmonary embolism	2.786187	0.342784	7
Cerebellar embolism	1.990134	0.232499	5
Mesenteric artery embolism	1.990134	0.232499	5
Iliac artery embolism	1.19408	0.124203	3
Air embolism	0.796054	0.07218	2
Renal vein embolism	0	0	0

Figure 7: Related Symptom Consistency (COVID monovalent : embolisms)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then no other vaccine generates a safety signal for any of these symptoms of embolism.

4.6 PRR for Stroke

. There are 18 "stroke" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 7 of them (LCI >= 2).

SYMPTOM	PRR	LCI	A
Pulmonary embolism	12.35622	11.20169	12790
Embolism	12.97567	7.762506	489
Peripheral embolism	42.19084	5.888375	106
Embolism arterial	7.960535	2.916243	80
Embolism venous	5.492769	2.890888	138
Cerebral artery embolism	4.59942	2.327782	104
Microembolism	15.12502	2.076593	38
Retinal artery embolism	8.756589	1.180286	22
Coronary artery embolism	4.776321	0.621039	12
Femoral artery embolism	3.582241	0.45383	9
Septic pulmonary embolism	2.786187	0.342784	7
Cerebellar embolism	1.990134	0.232499	5
Mesenteric artery embolism	1.990134	0.232499	5
Iliac artery embolism	1.19408	0.124203	3
Air embolism	0.796054	0.07218	2
Renal vein embolism	0	0	0

Figure 8: Related Symptom Consistency (COVID monovalent : stroke)

If we apply the same criteria to other vaccines (PRR >=2,LCI >=2, A >=10) then only COVID bivalent vaccine generates safety signals for stroke - for "embolic stroke" (LCI = 2.49), "lacunar stroke" (LCI = 4.74). No other vaccine generates any safety signals for stroke.

4.7 PRR for Haemorrhage

. COVID monovalent vaccines generate safety signals for 18 symptoms of haemorrhage (LCI >= 2).

SYMPTOM	PRR	LCI	A
Postmenopausal haemorrhage	61.954395	42.130876	4047
Uterine haemorrhage	7.5931258	5.11876073	496
Vaccination site haemorrhage	5.9058565	4.23356537	549
Subarachnoid haemorrhage	4.6967157	3.51899312	590
Conjunctival haemorrhage	4.5018199	3.44177984	656
Cerebral haemorrhage	3.9132087	3.36255437	1809
Vitreous haemorrhage	6.5176881	3.19220169	131
Vaginal haemorrhage	3.5154042	3.1696967	3524
Brain stem haemorrhage	12.736856	3.11766008	64
Haemorrhage urinary tract	4.692526	2.93772753	224
Eye haemorrhage	3.5303243	2.91128934	1020
Upper gastrointestinal haemorrhage	5.2105321	2.82233712	144
Basal ganglia haemorrhage	11.343763	2.76941072	57
Urinary bladder haemorrhage	10.348696	2.52068556	52
Cerebellar haemorrhage	6.129612	2.4808035	77
Vulval haemorrhage	17.513177	2.41284492	44
Internal haemorrhage	3.2927668	2.40825159	364
Genital haemorrhage	3.2339674	2.11641273	195

Figure 9: Related Symptom Consistency (COVID monovalent : haemorrhage)

In contract

1. RV vaccines generate safety signals for gastrointestinal and rectal haemorrhages;
2. DF vaccines have a safety signal for cerebral haemorrhages and internal haemorrhage;
3. HIBV, IPV and PNC13 have safety signals for subcutaneous haemorrhage.
4. HPV4 has a safety signal for genital haemorrhage

So whilst other vaccines have safety signals for only 2 or 3 symptoms of haemorrhage, COVID vaccines have safety signals for 18 symptoms of haemorrhage. This indicates that with COVID vaccines haemorrhage is taking place in many organs distributed throughout the body rather than in a few localised areas.

4.8 PRR for Bleeding

. COVID monovalent vaccines generates safety signals for 8 symptoms of menstrual bleeding (LCI >= 2).

SYMPTOM	PRR	LCI	A
Heavy menstrual bleeding	48.663831	40.6001928	14427
Intermenstrual bleeding	44.684357	31.8805336	3817
Polymenorrhoea	31.337973	21.8614043	2362
Oligomenorrhoea	14.299111	10.4438565	1437
Dysmenorrhoea	9.6755801	8.66263952	7949
Hypomenorrhoea	11.100524	7.56165308	753
Abnormal uterine bleeding	6.595872	3.07593943	116
Amenorrhoea	3.40617	3.05979395	3192
Gingival bleeding	1.5541997	1.29665389	574
Coital bleeding	3.7149164	1.12938244	28
Bleeding time prolonged	1.0879398	0.60220647	41
Eyelid bleeding	2.1891472	0.48522079	11
Nail bed bleeding	0.7391925	0.29491802	13
Bleeding anovulatory	1.1940803	0.24100047	6
Bleeding time abnormal	1.9901338	0.23249883	5
Menorrhagia	0.0433648	0.0293587	28

Figure 10: Related Symptom Consistency (COVID monovalent : menstrual bleeding)

The only other vaccine with safety signals for menstrual disorder is HPV - with safety signals for 3 symptoms. Perhaps the reason for the menstrual bleeding with COVID vaccines can be found by looking at what COVID and HPV vaccines have in common.

SYMPTOM1	HPV2	HPV4	HPV9	HPVX
Polymenorrhoea	0	0	0	0
Oligomenorrhoea	0	0	0	0
Dysmenorrhoea	2.712917	0	0	0
Hypomenorrhoea	0	0	0	0
Amenorrhoea	0	3.356000	0	2.336687
Menorrhagia	19.13372	53.30976	0	20.17658
Polymenorrhagia	0	0	0	0

Figure 11: Related Symptom Consistency (HPV vaccine : menstrual bleeding)

4.9 PRR for Aneurysm

. COVID 19 monovalent vaccines generate a safety signal for 4 symptoms of aneurysm (LCI >= 2).

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10)

SYMPTOM	PRR	LCI	A
Aneurysm ruptured	6.8659615	2.50570841	69
Aortic aneurysm	3.6727014	2.36551416	203
Ruptured cerebral aneurysm	5.7315853	2.31527877	72
Aortic aneurysm rupture	9.1546154	2.22225239	46
Aneurysm	2.6866806	1.74999496	162
Intracranial aneurysm	2.5208361	1.71520389	190
Cardiac aneurysm	3.9802676	1.42406775	40
Carotid artery aneurysm	4.3782943	1.02953167	22
Cerebral endovascular aneurysm repair	4.7763211	0.62103889	12
Splenic artery aneurysm	3.9802676	0.50950491	10
Aortic aneurysm repair	2.1891472	0.48522079	11
Retinal aneurysm	3.5822408	0.4538301	9
Coronary artery aneurysm	0.7076031	0.31269178	16
Vertebral artery aneurysm	2.3881605	0.28750413	6
Mesenteric artery aneurysm	1.1940803	0.1242032	3
Carotid aneurysm rupture	0.1990134	0.01804507	1

Figure 12: Related Symptom Consistency (COVID monovalent : aneurysm)

then no other vaccine generates a safety signal for any of these symptoms of aneurysm.

4.10 PRR for Arteriosclerosis

. There are 10 "arteriosclerosis" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 4 of them (LCI >= 2).

SYMPTOM	PRR	LCI	A
Aortic arteriosclerosis	7.960535	4.560661	260
Arteriosclerosis coronary artery	6.368428	3.636487	208
Carotid arteriosclerosis	11.01207	3.480296	83
Arteriosclerosis	2.82599	2.10181	355
Cerebral arteriosclerosis	4.908997	1.513587	37
Renal artery arteriosclerosis	0.796054	0.07218	2

Figure 13: Related Symptom Consistency (COVID monovalent : arteriosclerosis)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then no other vaccine generates a safety signal for any of these symptoms of arteriosclerosis.

4.11 PRR for Ischaemia

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There are 40 "ischaemic" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 8 of them (LCI >= 2).

SYMPTOM	PRR	LCI
Peripheral ischaemia	9.552642	4.903816635
Cerebellar ischaemia	9.154615	1.23627562
Ischaemic cerebral infarction	8.637181	4.582070772
Colitis ischaemic	8.048986	4.121657367
Ischaemic stroke	7.731164	6.425317684
Ischaemic cardiomyopathy	7.695184	2.411122273
Intestinal ischaemia	7.164482	3.789927106
Ischaemic hepatitis	4.875828	1.759580675
Spinal cord ischaemia	4.577308	1.079157386
Ischaemic limb pain	4.378294	0.56524642
Ischaemia	3.980268	2.767538215
Renal ischaemia	3.980268	0.509504909
Transient ischaemic attack	3.980268	3.518613112
Ocular ischaemic syndrome	3.582241	0.453830104
Optic ischaemic neuropathy	2.798626	1.932528007
Reversible ischaemic neurological deficit	2.487667	0.865761426
Cerebral small vessel ischaemic disease	2.447127	1.629371536
Retinal ischaemia	2.255485	0.946924061
Myocardial ischaemia	2.015325	1.583238159
Subendocardial ischaemia	1.990134	0.232498832
Cerebral ischaemia	1.959119	1.533411211
Brain stem ischaemia	1.691614	0.569198977
Hypoxic-ischaemic encephalopathy	1.094574	0.686032985
Necrosis ischaemic	0.530702	0.118774564
Gastrointestinal ischaemia	0.398027	0.024894852

Figure 14: Related Symptom Consistency (COVID vax : ischaemia)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then only COVID bivalent generates safety signals for Ischaemia - for "transient ischaemic attack" and for "myocardial ischaemia". No other vaccines generate any safety signals for any symptoms of ischaemia.

4.12 PRR for Haematoma

. COVID monovalent vaccines generate safety signals for 4 symptoms of haematoma (LCI >= 2). These include subdural, cerebral and vaccination site haematoma.

SYMPTOM	PRR	LCI
Subdural haematoma	3.900662	2.679124
Vaccination site haematoma	3.393702	2.425025
Cerebral haematoma	4.450663	2.401835
Spontaneous haematoma	4.726568	2.297102

Figure 15: Related Symptom Consistency (COVID monovalent : haematoma)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then there are 8 other vaccines that have a safety single for "injection site haematoma". It seems that for COVID monovalent vaccines haematomas effect regions beyond the injection site, particularly in the brain - since both subdural and cerebral haematomas are located there.

4.13 PRR for Phlebitis

. COVID monovalent vaccines generate safety signals for 4 symptoms of phlebitis (LCI >= 2).

SYMPTOM	PRR	LCI
Thrombophlebitis superficial	29.73828	14.1072
Phlebitis superficial	11.27742	3.565845
Thrombophlebitis	9.937829	6.940298
Phlebitis deep	5.174348	0.676871
Phlebitis	3.607512	2.781025
Periphlebitis	2.388161	0.287504
Papillophlebitis	0.995067	0.193051
Phlebitis infective	0.398027	0.024895
Portal vein phlebitis	0.199013	0.018045

Figure 16: Related Symptom Consistency (COVID monovalent : phlebitis)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then no other vaccine generates a safety signal for any symptoms of phlebitis.

4.14 PRR for Fibrin D Dimer

Biomarkers for thrombosis include the D-dimer test.

VAX_TYPE	PRR	LCI
COVID19-2	5.03321549	4.407369049
COVID19	3.724552044	3.340005204
UNK	1.381082434	0.990135348
PNC15	6.893029878	0.973384893
FLUA4	1.624082326	0.609413054
PNC20	1.389623358	0.448113561
FLU4	0.358228778	0.222459306
RSV	1.391798187	0.196104613
FLUX	0.251582761	0.139207051
FLUC4	0.378911881	0.122159492
VARZOS	0.147689345	0.098019135
PNC13	0.214179753	0.089096888
YF	0.311296792	0.04384269
FLUX(H1N1)	0.246669024	0.034739684
PPV	0.073045294	0.030385427
HPV9	0.118313373	0.029579087
FLU3	0.061490549	0.029294002
TYP	0.192332327	0.027086571
HEPAB	0.145186321	0.02044651
RAB	0.124095709	0.017476183
HPV2	0.08090634	0.011393701
HPV4	0.030461658	0.007615415
TDAP	0.027019262	0.003804927
6VAX-F	0	0
ADEN_4_7	0	0
ANTH	0	0

Figure 17: Related Biomarker Consistency (All vaccines : D-dimer)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then only COVID bivalent has a safety signal for D-dimer (LCI = 4.4). No other vaccine has a signal for D-dimer.

4.15 PRR for Anticoagulant Therapy

VAX_TYPE	PRR	LCI
COVID19-2	5.03321549	4.407369049
COVID19	3.724552044	3.340005204
UNK	1.381082434	0.990135348
PNC15	6.893029878	0.973384893
FLUA4	1.624082326	0.609413054
PNC20	1.389623358	0.448113561
FLU4	0.358228778	0.222459306
RSV	1.391798187	0.196104613
FLUX	0.251582761	0.139207051
FLUC4	0.378911881	0.122159492
VARZOS	0.147689345	0.098019135
PNC13	0.214179753	0.089096888
YF	0.311296792	0.04384269
FLUX(H1N1)	0.246669024	0.034739684
PPV	0.073045294	0.030385427
HPV9	0.118313373	0.029579087
FLU3	0.061490549	0.029294002
TYP	0.192332327	0.027086571
HEPAB	0.145186321	0.02044651
RAB	0.124095709	0.017476183
HPV2	0.08090634	0.011393701
HPV4	0.030461658	0.007615415
TDAP	0.027019262	0.003804927

Figure 18: Related Treatment Consistency (All vaccines : anticoagulant therapy)

COVID 19 monovalent vaccines have safety signal for ”anticoagulant therapy”. Anticoagulant therapy indicates clotting that requires this therapy.

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then the only other vaccine with a safety signal for ”anticoagulant therapy” is COVID bivalent (LCI = 4.4)

4.16 PRR for Thrombectomy

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VAX_TYPE	PRR	LCI
RSV	13.54172147	1.90363459
COVID19	5.233314752	3.53871583
COVID19-2	3.296675531	1.998409595
DTP	2.513638168	0.353194921
FLUN3	1.4347815	0.201594225
FLUC4	1.228231427	0.172571397
UNK	1.147240659	0.368361981
HPV2	0.787191083	0.110601459
HPV4	0.446797768	0.143457766
6VAX-F	0	0
ADEN_4_7	0	0
ANTH	0	0
BCG	0	0
CEE	0	0
CHOL	0	0
DF	0	0
DPP	0	0
DT	0	0
DTAP	0	0
DTAPH	0	0
DTAPHEPBIP	0	0
DTAPIPV	0	0
DTAPIPVHIB	0	0
DTIPV	0	0
DTOX	0	0
DTPHEP	0	0

Figure 19: Related Treatment Consistency (All vaccines : thrombectomy)

COVID 19 monovalent vaccines generate a safety signal for ”thrombectomy”
If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10)
then only COVID bivalent generates a safety signal (with an LCI of 1.998)

4.17 PRR for Catheters

. COVID monovalent generates 4 safety signals for use of catheters. Catheters are an indicator of blockage of blood vessels. (LCI >= 2).

VAX_TYPE	PRR	LCI
Catheterisation cardiac	6.413367	4.962255
Catheterisation cardiac abnormal	3.151045	2.333804
Arterial catheterisation	9.353629	2.271988
Catheter directed thrombolysis	8.358562	2.023327
Catheterisation cardiac normal	2.144922	1.604303
Central venous catheterisation	1.477292	1.087603
Vascular catheterisation	6.368428	0.844535
Bladder catheterisation	1.027288	0.82006
Catheter removal	4.776321	0.621039
Catheter placement	0.861037	0.613729
Transcatheter aortic valve implant	4.378294	0.565246
Biliary catheter insertion	2.786187	0.342784
Bladder catheter replacement	1.592107	0.338085
Catheter site haemorrhage	1.061405	0.281582
Bladder catheter removal	1.19408	0.241
Catheter site pain	1.592107	0.177944
Arterial catheterisation normal	1.19408	0.124203
Bladder catheter permanent	0.796054	0.07218
Bladder catheter temporary	0.796054	0.07218
Catheter culture positive	0.398027	0.024895
Catheter site discharge	0.398027	0.024895
Swan ganz catheter placement	0.398027	0.024895
Ureteral catheterisation	0.398027	0.024895
Catheter site erythema	0.199013	0.018045

Figure 20: Related Treatment Consistency (COVID monovalent : catheters)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then no other vaccine generates a safety signal for catheter.

4.18 PRR for Stents

. COVID monovalent generates two safety signals for use of stents, and two further safety signals for stenosis. Use of stents is an indicator of blockage of blood vessels.

VAX_TYPE	PRR 1	LCI 1
Stent placement	4.426058	2.939576
Coronary arterial stent insertion	2.905595	2.087972
Ureteral stent insertion	5.307023	1.641741
Vascular stent thrombosis	10.3487	1.404279
Arterial stent insertion	4.975334	1.178442
Bile duct stent insertion	2.985201	0.682654
Vascular stent stenosis	5.174348	0.676871
Venous stent insertion	2.786187	0.342784
Cerebral artery stent insertion	1.592107	0.177944
Stent removal	1.592107	0.177944
Aortic stent insertion	1.592107	0.177944
Vascular stent insertion	1.592107	0.177944
Pancreatic stent placement	0.796054	0.07218
Brain stent insertion	0.398027	0.056065

Figure 21: Related Treatment Consistency (COVID monovalent : stents)

If we apply the same criteria to other vaccine (PRR >=2,LCI >=2, A >=10) then only COVID bivalent has a safety signal - for "coronary artery stent insertion" (LCI = 2.12)

5 Summary

This pilot study provides a publicly accessible dataset where anyone can check the safety signals for any vaccine. Safety signals are defined by the magnitude of the PRR (PRR > 2), where the lower confidence interval of the PRR is also greater than or equal to 2 (LCI >= 2), and where there are atleast 10 reported instances of the symptom. High PRR scores are confirmed by consistency of the PRR across multiple samples, related symptoms, indicators and treatments. In the demonstration example, I find that COVID 19 vaccines show the highest disproportionality for thrombosis, and this is confirmed by elevated PRR scores for related symptoms and treatments.

COVID 19 vaccines are strongly associated with severe vascular disease characterised by occlusion of blood vessels, and weakening and rupture of blood vessel walls

Occlusion takes the form of thombosis, embolism, infarction. Occlusion leads to ischaemia and localised haematoma. Weakeneing and rupture of blood vessels leads to haemorrhages, bleeding and strokes.

COVID bivalent vaccines also show safety signals for vascular disease, but to a lesser extent than COVID monovalent vaccines.

HPV vaccines are the only vaccines besides COVID monovalent vaccines to have safety signals for menstrual disorder.

6 Summary of Signals

Please find here brief summary of the safety signals found for other vaccines in VAERS [3]

7 CDC Finally Release their PRR Analysis

Please find here information regarding the CDC's own findings from their PRR analysis of VAERS data. [24] [25]

8 Numbers for PRR and LCI Calculations

Please find here the spreadsheets for a selection of symptoms related to thrombosis showing the numbers upon which PRR and LCI calculations are based [26]

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